



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,743	03/29/2005	Jean-Thierry Simonnet	267329US0PCT	8358
22850	7590	02/04/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER KASSA, TIGABU	
			ART UNIT	PAPER NUMBER
			1619	
			NOTIFICATION DATE	DELIVERY MODE
			02/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/529,743	Applicant(s) SIMONNET, JEAN-THIERRY	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-66 and 68-86 is/are pending in the application.
- 4a) Of the above claim(s) 41-60, 81-83 and 86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-66, 68-80 and 84-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed August 19, 2008. **Claims 41-66, and 68-86 are currently pending. Claims 61-66, 68-80 and 84-85 are under consideration in the instant office action.** Claims 41-60, 81-83, and 86 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 1-40 and 67 are cancelled. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is FINAL.

Withdrawn rejections:

Applicant's amendments and arguments filed on 10/15/08 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments and persuasive arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-65, 70, 72-73, and 78-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Seo et al. (WO 01/12718).

Instant claim 61 recites a cosmetic composition comprising at least one aqueous phase, at least one lipophilic compound and at least one block amphiphilic copolymer comprising at least one nonionic hydrophilic polymer block and at least one hydrophobic polymer block. Instant claim 62 recites in the composition the block amphiphilic copolymer is the sole solvent for the

Art Unit: 1619

lipophilic compound. Instant claim 63 requires in the composition the molecular weight of the block copolymer is between 1,000 and 100,000. Instant claim 64 in the composition the weight ratio of the ionic or nonionic hydrophilic polymer block to the hydrophobic polymer block is between 1/100 and 50/1. Instant claim 65 recites in the composition the weight concentration ratio between the lipophilic compound and the block copolymer is between 0.005 and 0.5.

Instant claim 70 recites in the composition the hydrophobic polymer block is selected from the list recited in the instant claim. Instant claim 72 recites the incorporation of lipophilic compound from the list recited in the instant claim. Instant claim 73 recites the incorporation of lipophilic compound from the list recited in the instant claim. Instant claim 78-79 recite the incorporation of lipophilic compound from the list recited in the instant claims. Instant claim 80 recites the incorporation of formulation adjuvants in the composition from the list recited in the instant claim.

Seo et al. teach a composition comprising **a block copolymer containing a hydrophilic and a hydrophobic polymer block** (abstract). The composition comprises an amphiphilic block copolymer has a hydrophilic poly(alkylene glycol), which is a nonionic polymer and a hydrophobic biodegradable polymer component (abstract). The amphiphilic block copolymer as described through out the document does not comprise an ionic water-soluble polymer block. The amphiphilic polymer **solubilizes poorly water soluble drugs (e.i. lipophilic compounds) in aqueous media** (abstract). Preferred **hydrophobic polymer may be, e.g., polycaprolactone (page 6)**. Preferred molecular weights of polymers to be used for **oral, ophthalmic or external use are 1000-10000 (page 7)**. The hydrophilic portion of the block polymer is preferably 40-70% which the examiner calculates is a **1/1.5 to 2.3/1 ratio of hydrophilic to hydrophobic**

Art Unit: 1619

polymer blocks (page 6). The lipophilic compound is more preferably 5-30% by weight of the block copolymer which the examiner calculates is **a weight ratio of 0.05-0.3** (page 4). Examples of lipophilic compounds included in the composition are **anti-inflammatory agents, antifungal agents, and sex hormones** (page 8). Specific examples include **aspirin, testosterone and progesterone** (page 8). **Organic solvents** may optionally be included in the composition (page 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1619

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al.

(WO 01/12718) as applied to claims 61-65, 70, 72-73, and 78-80.

Applicant Claims

Instant claim 61 recites a cosmetic composition comprising at least one aqueous phase, at least one lipophilic compound and at least one block amphiphilic copolymer comprising at least one of an ionic or a nonionic hydrophilic polymer block and at least one hydrophobic polymer block. In further limitations instant claim 65 recites in the composition the weight concentration ratio between the lipophilic compound and the block copolymer is between 0.005 and 0.5. In additional further limitation instant claim 84 requires in the composition the weight concentration ratio between the lipophilic compound and the block copolymer is between 0.005 and 0.02.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

As discussed above Seo et al. address all the limitations of instant claim 61 and 65. Specifically, Seo et al. teach the incorporation of the lipophilic compound in range of 0.1-50% (page 4). The examiner calculates that this is a weight ratio of 0.001-0.5.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

The range for incorporating the lipophilic compound as taught by Seo et al. is not exactly the same range as in instant claim 84 although the ranges overlap.

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been *prima facie* obvious for the ordinary person skilled in the art at the time the invention was made to routinely optimize various weight values for the block copolymer and the lipophilic compound, since it is a routine practice performed by the skilled artisan. Moreover, based on (see MPEP 2144.05 *In re Aller*, 220 F. 2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)) “differences in concentration (weight values and ratios in the case of the instant application) will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical, and also since the general conditions of the instant claim 84 are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” The skilled artisan would have been motivated to optimize the concentration of the lipophilic compound to maximize the effectiveness of the composition. The skilled artisan would have a reasonable expectation of success because the ranges taught in instant claim 84 overlap with the concentration range taught by Seo et al.

Claims 66, 68-69, 71, and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/12718) as applied to claims 61-65, 70, 72-73, and 78-80 above, and further in view of L’Alloret (US Patent No. 6,994,846).

Applicant Claims

The limitations of instant claim 61 are delineated above. Instant claim 66 recites in the composition the hydrophobic polymer block comprises one or more polymerized monomer units from the list recited in the claim. Instant claim 68 recites in the composition the hydrophobic block copolymer is nonionic and selected from the list recited in instant claim 68. Instant claim

Art Unit: 1619

69 recites in the composition the amphiphilic copolymer comprises at least one nonionic hydrophilic polymer block one selected from the group consisting of polyethylene oxide and polyvinylpyrrolidone. Instant claim 71 recites in the composition the block amphiphilic copolymer is selected from the list recited in the instant claim. Instant claim 75 recites the incorporation of sunscreen from the list recited in the instant claim. Instant claim 76 recites the incorporation of 1,3,5-triazine derivative from the list recited in the instant claim. Instant claim 77 recites the composition further comprises butylmethoxydibenzoylmethane.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Seo et al. are disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

This differ from the instant claims in that Seo et al. do not teach the specific hydrophobic polymers disclosed in instant claim 66, the specific hydrophobic polymers disclosed in instant claims 68 and 69, nor of the amphiphilic polymers taught in instant claim 71. Seo et al. do not teach the incorporation of the sunscreen agents listed in instant claim 75. These deficiencies are cured by the teachings of L'Alloret.

L'Alloret teaches a block copolymer comprising both a water soluble block and a hydrophobic polymer block (abstract). The hydrophobic portion may be made from methyl methacrylate, ethyl methacrylate, n-butyl methacrylate, tert-butyl (meth)acrylate, cyclohexyl acrylate, isoboronyl acrylate and 2-ethylhexyl acrylate, and trifluoromethyl (meth)acrylate (column 8, line 62-column 9, line 3). Water soluble monomers include (meth)acrylamide, N-vinylacetamide, N-methyl-N-vinylacetamide, N-vinylformamide, and N-methyl-N-

Art Unit: 1619

vinylformamide (column 9, lines 46-49). Additional water soluble blocks may be polyoxyalkylenated polymers including both homo and copolymers (column 11, lines 59-64). Active agents which may be included in the composition are anti-inflammatory agents, vitamins DHEA and derivatives of DHEA (column 17 lines 29-50). Sunscreens which may be included in the composition are p-aminobenzoic acid derivatives, salicylic acid derivatives, dibenzoylmethane derivaives, cinnamic derivatives, denzophenone derivatives, benzylidenecamphor derivatives, phenylbenzimidazole derivatives, triazine derivatives, phenylbenzotriazole derivatives, anthranilic derivatives, imidazoin derivatives (column 18 line 34 column 20, line 23).

L'Alloret also teaches as discussed above the use of polystyrene as the hydrophobic block of the amphiphilic block polymer and the use of polyethylene oxide (polyoxyethylene), which address instant claim 71. L'Alloret also teaches the composition also comprises active agents such as anti-inflammatory agents, vitamins etc (column 17, line 28-50), which addresses instant claim 72. L'Alloret also teaches the composition also comprises sunscreen agents such as benzophenone derivatives (column 19, lines 14-30), triazine derivatives (column 19, lines 51-57) etc, which addresses instant claim 75. L'Alloret also teaches the composition also comprises 1,3,5-triazine derivatives such as diethylhexylbutamidotriazone (column 20, line 21), which is 2-[(p-(tert-butylamido)anilino)-4,6-bis[(p-(2'-ethylhexyl-1'-oxycarbonyl)- anilino]-1,3,5-triazine, which addresses instant claim 76. L'Alloret also teaches the composition comprises organic UV screening agents that more particularly preferred and the list contains butylmethoxydibenzoylmethane (column 20, lines 6-9), which addresses instant claim 77.

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

Art Unit: 1619

It would have been prima facie obvious to modify the teachings of Seo et al. to incorporate the hydrophilic and hydrophobic polymer blocks taught by L'Alloret because both Seo et al. and L'Alloret teach compositions comprising amphiphilic block polymers and lipophilic compounds. The skilled artisan would have been motivated to modify the block polymers to optimize the solubility of the lipophilic compound. Alternatively the skilled artisan could modify the polymers to optimize the composition for a particular application. The skilled artisan would have a reasonable expectation of success because Seo et al. and L'Alloret use some of the same types of lipophilic compounds in the compositions with the comprising amphiphilic block polymers.

It would have been prima facie obvious to modify the teachings of Seo et al. to incorporate other lipophilic compounds including the sunscreen agents because L'Alloret teach the incorporation of lipophilic compounds such as sunscreen agents. The skilled artisan would have been motivated to incorporate sunscreen agents because sunscreen agents are important for human health and the prevention of skin cancer. The skilled artisan would have had a reasonable expectation of success because Seo et al. and L'Alloret teach compositions comprising amphiphilic block copolymers and lipophilic compounds including some of the same types of lipophilic compounds.

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/12718) as applied to claims 61-65, 70, 72-73, and 78-80 above, and further in view of Guiramand et al. (US Patent Application Publication 2003/0027864).

Applicant Claims

Instant claim 61 recites a cosmetic composition comprising at least one aqueous phase, at least one lipophilic compound and at least one block amphiphilic copolymer comprising at least one of an ionic or a nonionic hydrophilic polymer block and at least one hydrophobic polymer block. In further limitation instant claim 73 recites the incorporation of lipophilic compound from the list recited in the instant claim. In additional further limitation instant claim 74 requires the composition further comprises at least one salicylic acid derivative from the list given in the claim.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

As discussed above Seo et al. address all the limitations of instant claims 61 and 73.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

This differs from the claimed limitation in instant claim 74 in that Seo et al. do not teach the types of salicylic acid derivatives recited in the instant claim. These deficiencies are cured by Guiramand et al. (US 2003/0027864).

However, Guiramand et al. discloses a cosmetic composition comprising salicylic acid derivatives 5-n-decanoylsalicylic, 5-n-dodecanoylsalicylic, 5-n-octylsalicylic etc (see claim 14).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been *prima facie* obvious for the ordinary person skilled in the art at the time the invention was made to modify the composition of Seo et al. by incorporating salicylic acid derivatives selected from the list recited in the instant claim as taught by Guiramand et al., because the salicylic acid derivatives are one of the many insoluble organic compounds. The

Art Unit: 1619

skilled artisan would have been motivated to incorporate the salicylic acid derivatives taught by Guiramand et al. because useful for repairing the main manifestations of ageing of the skin (page 5, paragraph 0092). The skilled artisan would have had a reasonable expectation of success because Seo et al. already teach the incorporation of aspirin which is one derivative of salicylic acid.

Claim 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/12718) as applied to claims 61-65, 70, 72-73, and 78-80 above, and further in view of Grollier et al. (US Patent No. 5,246,693).

Applicant Claims

Instant claim 61 recites a cosmetic composition comprising at least one aqueous phase, at least one lipophilic compound and at least one block amphiphilic copolymer comprising at least one of an ionic or a nonionic hydrophilic polymer block and at least one hydrophobic polymer block. In a further limitation instant claim 72 requires the incorporation of lipophilic compound from the list given in the claim. In additional further limitation instant claim 85 requires the lipophilic compound is selected from essential oils selected from the list recited in instant claim 85.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

As discussed above Seo et al. address all the limitations of instant claims 61 and 72.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Art Unit: 1619

This differs from the claimed limitation in instant claim 85 in that Seo et al. do not disclose the same essential oils recited in the instant claim. These deficiencies are cured by Grollier et al. (US Patent No. 5246693).

However, Grollier et al. disclose a cosmetic composition comprising essential oils selected from eucalyptus, lavandin, lavender, vetiver, litsea cubeba, lemon, sandalwood, red or white thyme, rosemary, camomile, savory, nutmeg, cinnamon, hyssop, caraway and orange, clove, mint, rose and parsley seeds (column 3, 21-26).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been *prima facie* obvious for the ordinary person skilled in the art at the time the invention was made to modify the composition of Seo et al. by incorporating essential oils selected from the list recited in the instant claims, because the essential oils are also lipophilic compounds. The skilled artisan would have been motivated to include essential oils such as those taught by Grollier et al. because they are known to safely provide moisture to humans. The skilled artisan would have had a reasonable expectation of success because both Seo et al. and Grollier et al. teach compositions comprising amphiphilic compounds for enhancing solubility of poorly soluble lipophilic compounds.

Conclusion

Claims 61-66, 68-80 and 84-85 are rejected, while claims 41-60, 81-83, and 86 are withdrawn. Claims 1-40 and 67 are cancelled. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1619

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

01/28/09

/Mina Haghighatian/
Primary Examiner, Art Unit 1616